

NZ 00/00135

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CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Provisional Specification as filed on 21 July 1999 with an application for Letters Patent number 336856 made by BOMAC LABORATORIES LTD.

Dated 23 August 2000.

**PRIORITY
DOCUMENT**

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Neville Harris
Commissioner of Patents



336856

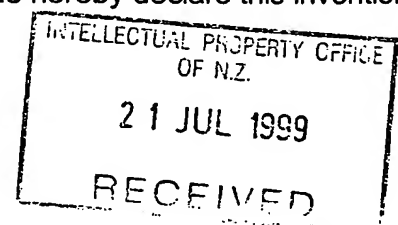
Patents Form No. 4
Application Fee \$ 50.00
James & Wells ref: 16341

Patents Act 1953

PROVISIONAL SPECIFICATION

IMPROVEMENTS IN AND RELATING TO ANTI-INFLAMMATORIES

We, BOMAC LABORATORIES LTD, a New Zealand company of corner Wiri Station Road and Hobill Avenue, Manukau City, Auckland, New Zealand, do hereby declare this invention to be described in the following statement:



TECHNICAL FIELD

The present invention relates to compositions and dietary supplements for small animals such as pets. Preferred compositions and supplements are directed to cats and dogs. Preferred embodiments afford anti-inflammatory properties and may find particular use for older animals, though some preventative effects may be afforded to younger animals over time.

BACKGROUND ART

Many domestic pets suffer similar afflictions to humans, particularly in their later years. It is not uncommon for many pets such as cats and dogs, to suffer afflictions such as inflammation of the joints, and arthritis, etc. Treatment of these afflictions often follows a medical approach where pharmaceutical compounds are administered in the form of medicaments to the animal. In most cases, the afflictions are treated after diagnosis until such time as the condition has been alleviated or suitably addressed.

It is one object of the present invention to provide the public with a useful alternative to the methods and compositions used to address afflictions, and particularly those associated with inflammation, in domestic animals.

It is also an object of the invention to provide a supplement or composition which may be administered on a regular basis and which can address the aforesaid afflictions, and which may also exhibit some preventative properties.

Further aspects and advantages of the present invention will become apparent from the ensuing description which is given by way of example only.

DISCLOSURE OF INVENTION

According to one aspect of the present invention there is provided a composition for administration to animals which includes an extract of green-lipped mussel in combination with at least one of: deer velvet (and/or extract thereof), ENZOGENOL, and shark cartilage (and/or an extract thereof).

According to another aspect of the present invention there is provided a composition, substantially as described above, which is incorporated into a foodstuff to be consumed by an animal.

According to another aspect of the present invention there is provided a composition, substantially as described above, in the form of a tablet or capsule to be administered to the animal.

According to a further aspect of the present invention, there is provided a method for addressing inflammation in animals, comprising the administration of the composition containing at least green lipped mussel extract.

According to another aspect of the present invention, there is provided a method of redressing inflammation in animals, substantially as described above, in which at least one of: deer velvet and/or extract thereof, shark cartilage and/or extract thereof, and an anti-oxidant is co-administered to the animal.

A preferred form of the present invention is as a tablet or capsule, or similar dosage form, which may be administered orally to an animal. Another preferred form of the present invention is in the form of a foodstuff which will be consumed by an animal. Standard

techniques for the manufacture of dosage forms, and foodstuffs, may be followed.

Biscuits for animals are relatively common for many small pets, and this is another preferred form of the invention. Standard techniques for the manufacture of these biscuits may be used.

Many small pets lead relatively active lives, and suffer from bone and joint stress as a consequence of these activities. In later life, extra care is required to maintain mobility and the health of the animal. The present invention seeks to provide one or more naturally occurring substances, as an alternative to the administration of pharmaceuticals, and which can be administered regularly to animals to help address such problems. It is considered that regular use of the embodiments of the present invention may help reduce the likelihood or seriousness of joint and inflammatory problems in animals in their later years, though it is also envisaged that some embodiments of the present invention will also be administered to animals suffering from such problems, so as to provide some alleviation and therapeutic effect.

Preferred embodiments of the present invention include an extract of green lipped mussel. In addition, other embodiments may include other components which can assist and enhance the properties and effects afforded by the use of green lipped mussel extracts. In particular, the following components find use in embodiments of the present invention.

GREEN LIPPED MUSSEL EXTRACT

The main activity of green lipped mussel extract is due to a glycogen complex that can be demonstrated to suppress inflammation. This anti-inflammatory activity is considered to be due to an neutrophil-blocking action. A second activity involves the inhibition of pro-

inflammatory prostaglandin synthesis. This is due to the natural presence of the fatty acid - eicosatetraenoic acid. There is also a third activity due to the natural glycosaminoglycan content, which includes chondroitin sulphate, hyaluronic acid, and glucosamines.

DEER VELVET

This may include deer velvet and extracts thereof in various forms. The primary function is to promote blood cell growth as well as influencing cardio-vascular function and the immune system.

The functions of antler velvet are many, but generally fall into the major categories of general body strengthening, healing, promoting blood cell growth, including the immune system, and influencing cardio-vascular function.

Antler velvet growth factors involved with the growth of blood vessels act to prevent leakage of fluids and hence lower swelling in cases of inflammation. Deer velvet includes anti-inflammatory agents, though the mechanisms for their action are not yet known. The antler velvet also has an immuno-stimulating action and affords an ability to improve the immune system's reaction to challenge pathogens.

ENZOGENOL™

This is a commercial formulation of Enzo Nutraceuticals Ltd, of Christchurch, comprising anti-oxidants, and is significantly more effective than Vitamin E. Oxidant and free-radical damage can be addressed by this formulation. Both oxidant and free-radical damage have been shown to be involved in premature ageing and, in particular, joint disease.

ENZOGENOL is based on anti-oxidants derived from a bark of selected *pinus radiata*. In

particular, the formulation includes natural anti-oxidants from the bark, which are among the more powerful yet discovered, with an activity of 50 times that of vitamin E. The use of anti-oxidants, such as ENZOGENOL, are useful for detoxifying oxidant substances which are naturally produced as part of the organisms functioning, as well as increased levels of oxidants which may accompany inflammation in certain disorders.

Other anti-oxidants of comparable activity or efficiency may be used in addition, or instead of ENZOGENOL.

SHARK CARTILAGE

This is used as a nutritional adjunct for assisting in the prevention of osteo-arthritic problems. In particular, the presence of glucosamines, chondroitin sulphate, and mucopolysaccharides assist in the production of cartilage, the alleviation of joint inflammation, and in the prevention of arthritis.

The use of shark cartilage not only confers some anti-inflammatory properties, but also is useful in addressing diseases or afflictions that are caused by, or dependent upon, angiogenesis (the development of blood vessels), such as osteo-arthritis, rheumatoid-arthritis, psoriasis, and others.

Various embodiments of the present invention are possible, and these will now be described by way of example only.

BEST MODES FOR CARRYING OUT THE INVENTION

Example 1: Compositions for adult dogs

This comprises a tablet (or similar dosage form) or dietary foodstuff which includes green lipped mussel extract. Ideally, the composition also includes a range of vitamins and trace minerals in a balanced proportion, ideal for targeted animal range. Different embodiments may contain different ratios, depending upon the size, type, or age of the animal.

Example 1a: Active constituents

In this embodiment, each tablet contains:

Green Lipped Mussel Extract	50 ± 15 mg
Vitamin mix	200 ± 200 mg
consisting of:	
Vitamin A	2000iu
Vitamin D3	300iu
Vitamin E	20iu
Vitamin K	0.5mg
Thiamine (Vitamin B1)	1mg
Riboflavin	2mg
Pyridoxine	0.5mg
Panthenic acid	2mg
Niacin	7mg
Biotin	0.75mg
Vitamin B12	0.15mg
Folic acid	0.1mg
Iron	12mg
Copper	1.5mg
Cobalt	0.25mg
Manganese	3mg
Zinc	25mg
Iodine	0.5mg
Selenium	0.075mg
Calcium	13.85mg

Suggested once daily dosage	
5 - 10 kg	1 tablets
11 - 15 kg	2 tablets
16 - 20 kg	3 tablets
21 - 25 kg	4 tablets
26 - 45 kg	5 tablets
45 - 65 kg	6 tablets

Can be administered directly into the mouth or added to the food.

This example is illustrative only for a composition directed to adult dogs. The vitamin mix is illustrative of a typical balance for adult dogs, but can be varied (and components added or eliminated) in different embodiments.

Example 2: Growing Puppies

This embodiment is also in the form of a foodstuff, or in a dosage form for the animal. For ease of administration, it is anticipated that preferred embodiments will be in the form of a foodstuff to be ingested by the puppies.

Preferred embodiment include green lipped mussel extract in combination with deer velvet, or an extract thereof.

Preferred embodiments will also include a balanced range of vitamins and trace elements appropriate to growing puppies.

Example 2a: Active Constituents

Each tablet contains:

Green Lipped Mussel Extract	50 ± 20 mg
Deer Velvet	25 ± 10 mg
Vitamin mix (see example 1a)	200 ± 200 mg
Suggested once daily dosage	
5 -10 kg	1 tablets
11 - 15 kg	2 tablets
16 - 20 kg	3 tablets

May be fed in conjunction with Example 1a formulation. Can be administered

directly into the mouth or added to the food.

Example 3: for older or arthritic dogs...

These embodiments may also be in dosage forms, or foodstuffs. This range of embodiments are targeted at older animals, and particularly those that may be showing joint problems or arthritis.

These embodiments combine green lipped mussel extract with shark cartilage or extracts thereof. Ideally, the shark cartilage, or any extract thereof, should include glycosaminoglycans. These two active components act as powerful anti-inflammatories, and provide anti-inflammatory action over the use of the green lipped mussel extract alone.

Optionally but ideally also, deer velvet or extract thereof is included in the these formulations.

Ideally also, these embodiments will also include ENZOGENOL (proprietary formulation of anti-oxidants).

Example 3a: Active Constituents

Each tablet contains:

Green-Lipped Mussel Extract	175 ± 75 mg
Deer Velvet	25 ± 10 mg
Shark Cartilage	100 ± 50 mg
ENZOGENOL (™)	5 ± 2 mg
Vitamin mix (see example 1a)	200 ± 200 mg

Suggested once daily dosage

5 - 10 kg	1 tablets
11 - 15 kg	2 tablets

16 - 20 kg	3 tablets
21 - 25 kg	4 tablets
26 - 45 kg	5 tablets
45 - 65 kg	6 tablets

May be fed in conjunction with Example 1a-formulation. Can be administered directly into the mouth or added to the food.

Example 4: for cats

The preferred embodiment for cats will include green lipped mussel extract. This acts in the role of an anti-inflammatory to improve mobility, as well as relief from sore and arthritic joints. Again, preferred embodiments of this range will also include a balanced range of vitamins and trace minerals for cats.

Example 4a: Active Constituents

Each tablet contains:

Green Lipped Mussel Extract	175 ± 75 mg
Taurine	100 ± 50 mg
Potassium gluconate	70 ± 20 mg
Thiamine hydrochloride	25 ± 10 mg
Yeast	50 ± 20 mg
Dextrose (as a tableting agent)	
Vitamin mix (see example 1a)	optional

MODE OF ACTION

Taurine, an essential dietary ingredient in cats, is fundamental in preventing heart and eye disease. Taurine is also an important part of bile in the cat's digestive system.

Potassium Gluconate helps prevent hypocalcaemia, a common diet related deficiency in cats.

Thiamine helps prevent diseases related to thiamine deficiency such as diarrhoea, kidney disease and polioencephalomalacia.

Yeast provides a rich source of B vitamins and other natural products.

Dextrose is included as a tableting agent, instead of the more commonly used lactose, because many cats are lactose intolerant.

Suggested once daily dosage	
2.5 kg	1 tablets
> 2.5 kg	2 tablets

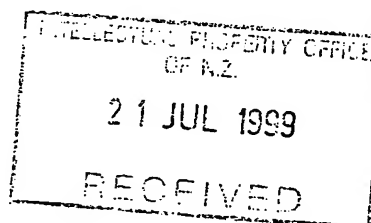
Can be administered directly into the mouth or added to the food.

It is also possible to use the compositions of examples 1 through 3 for cats though it is envisaged that in many cases, the use of green lipped mussel extract alone will be sufficient for the needs of most cats.

Aspects of the present invention have been described by way of example only and it should be appreciated that modifications and additions may be made thereto without departing from the scope thereof.

BOMAC LABORATORIES LTD
by their authorised agents
JAMES & WELLS

per:



Two handwritten signatures in black ink. The first signature is a cursive "G. Henry" and the second is a stylized "P".